

REMARKS

The pending Office Action addresses and rejects claims 1-6, 11-13, 15, 24, and 37-40. Applicants respectfully request reconsideration in view of the remarks herein.

Amendments to the Claims

Applicants amend the dependencies in claims 3-6 and 11-13 to provide proper antecedent basis and to more clearly claim the invention. Support for these amendments can be found throughout the specification and drawings. No new matter is added.

Claim Rejections Pursuant to 35 U.S.C. § 102(b)

Claims 39-40 are rejected pursuant to 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,066,154 ("Reiley"). Applicants respectfully disagree.

Claim 39 recites an intervertebral fusion device that includes a body having a proximal portion along a major axis of the body and a distal portion along the major axis. The body defines a conduit substantially parallel to the major axis and the conduit extends throughout the body. The device also includes a selectively expandable balloon at the distal portion that is configured to support vertebrae in a distracted position while the vertebrae fuse. An inner volume of the expandable balloon is in fluid communication with the conduit defined by the body and the balloon is formed of a biodegradable polymer.

1. Reiley lacks a biodegradable polymer

Reiley fails to teach or even suggest the device of claim 39 because it lacks a balloon formed of a biodegradable polymer. The Reiley specification identifies several materials from which the balloon can be formed, however none of those listed are biodegradable, much less biodegradable polymers. *Reiley* at col. 5, lns. 23-31; col. 9, lns. 28-33. Instead, Reiley teaches that that balloon material should be chosen merely by its ability to fold up during insertion and to withstand high inflation pressures. *Reiley* at col. 3, lns. 59-63. Moreover, the Reiley device is a surgical tool that is only temporarily inserted into the patient during surgery. *Reiley* at col. 10, lns. 10-13. There are no

significant benefits to forming such devices of a biodegradable material and doing so would in fact be detrimental as reuse of the device in subsequent procedures would be limited.

2. *Reilly is incapable of supporting vertebrae in a distracted position while they fuse*

Reiley also lacks a balloon that is configured to support vertebrae in a distracted position while the vertebrae fuse, as further required by claim 39. Instead, Reiley teaches a balloon that is inserted into a cavity formed in a pathologically weakened bone. *Reiley* at col. 3, lns. 42-54. The balloon is inflated to compress the soft cancellous bone within the cavity and is then removed to permit bone fortifying cement to be introduced. *Reiley* at col. 3, ln. 42 – col. 4, ln. 7; col. 10, lns. 10-13. Since the Reiley balloon is inserted within a single vertebral body and not between adjacent vertebrae, it is not configured to maintain distraction. Also, there is no indication that the balloon of Reiley, designed only to compress soft bone, could withstand the immense inflation pressures that would be required to maintain vertebrae in a distracted position, especially in light of the forces to which the vertebrae are subjected during daily activities.

Even if Reiley could be construed to teach a balloon of sufficient strength, it would still be incapable of supporting distracted vertebrae while they fuse because there is no way to introduce fusion material in Reiley without first removing the balloon. (The balloon in Reiley will not biodegrade over time, meaning any fusion material introduced would not be able to reach the bone itself.) In addition, presumably because the device is only intended for transient insertion, there is no means for detaching the Reiley balloon (12) from the catheter (21). *See Reiley* at FIG. 1. There is thus no practical way to close an incision while the Reiley balloon is left within the patient to support vertebrae during the lengthy fusion process. Reiley is therefore incapable of supporting vertebrae in a distracted position while they fuse and thus lacks yet another limitation of claim 39.

Accordingly, independent claim 39 distinguishes over Reiley and represents allowable subject matter. Claim 40 is allowable at least because it depends from an allowable base claim.

Claim Rejections Pursuant to 35 U.S.C. § 102(e)

Claims 1, 15, and 37 are rejected pursuant to 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,695,760 (“Winkler”). Applicants respectfully disagree.

Independent claim 1 recites an intervertebral fusion device that includes a body that has a proximal portion along a major axis and a distal portion along the major axis. The body defines a conduit substantially parallel to the major axis and the conduit extends throughout the body. The device also includes a support at the distal portion that is configured to support vertebrae in a distracted position while the vertebrae fuse. The support includes a conduit that is in fluid communication with the conduit defined by the body and that has at least one outlet on a surface of the support. The distal portion of the body is configured to selectively engage the support and at least a portion of the body or the support has a height distinct from a width taken along a cross-section of the portion of the body or support perpendicular to the major axis. The portion of the body or the support can distract vertebrae, between which the portion has been placed, by rotation of the body or the support about the major axis.

1. *The Winkler support (20) cannot form the claimed support*

Winkler fails to teach or even suggest the device of claim 1 because it lacks a support that includes a conduit in fluid communication with a conduit defined by a body. The Examiner argues that the structural support (20) shown in FIG. 2 of Winkler forms such a support and that the Winkler catheter (12) forms the claimed body, however these structures do not have conduits in fluid communication with each other. *Winkler* at FIG. 1. While the catheter (12) of Winkler does form a conduit (18), the conduit (18) is not in fluid communication with any portion of the support (20), much less a conduit included therein. *Winkler* at FIGS. 1, 3. Instead, the sole outlets of the conduit (18) – a pair of inflation ports (48, 54) – only permit fluid communication with a respective pair of balloons (46, 52). *See Winkler* at FIG. 3; col. 5, lns. 4-7. In other words, the Winkler balloons (46, 52) effectively serve as a fluid-tight seal around the distal end of the conduit (18), thereby preventing any fluid communication between the catheter conduit (18) and the support (20). Accordingly, the conduits of the Winkler support and the Winkler body are not in fluid communication, as required by claim 1.

Moreover, contrary to the Examiner's assertion, the distal end of the Winkler catheter (12) is not configured to selectively engage the support (20), as further required by claim 1. Instead, as shown in FIG. 1 of Winkler, only the balloon anchoring element (46) engages the support (20). *See also Winkler* at col. 5, lns. 8-22. While it is true that the catheter (12) could possibly touch or contact

the support (20), there is no indication that it is configured to selectively engage or interlock with it. If the mere possibility of contact were sufficient to constitute selective engagement, as the Examiner suggests, the term loses all meaning. Accordingly, Winkler is also deficient with respect to claim 1 because it lacks a body with a distal portion configured to selectively engage a support.

2. *The Winkler balloon (46) cannot form the claimed support*

The Examiner also presents an alternative argument that the balloon (46) of Winkler forms the claimed support. Claim 1, however, further requires that the support include a conduit with at least one outlet on a surface of the support. The Winkler balloon (46) altogether lacks such an outlet, and is thus likewise incapable of forming the claimed support. Instead, the Winkler balloon (46) has a solid, unbroken surface with no outlets whatsoever. *See Winkler* at FIGS. 1, 3, 4B; col. 5, lns. 1-15. This is by necessity, as even a single outlet in the Winkler balloon would allow inflation gas or fluid to escape, making inflation impossible. *See id.*

The balloon (46) of Winkler cannot form the claimed support for several other reasons as well. For example, Winkler fails to teach the catheter (12) being configured to selectively engage the balloon (46) and fails to teach the catheter (12) or the balloon (46) having a height distinct from a width, both of which are additional requirements of claim 1. Furthermore, claim 1 requires that at least a portion of the body or the support have a height distinct from a width whereby the portion can distract vertebrae by rotation of the body or the support about a major axis. Neither the catheter (12), nor the balloon (46) of Winkler are capable of distracting vertebrae by rotation about the major axis because both are of a symmetrical cross section and thus would have no distraction effect if rotated. *Winkler* at FIG. 3.

3. *Winkler lacks a conduit that extends throughout a body*

Winkler also fails to teach or suggest the device of claim 1 because it lacks a conduit that extends throughout the body. To the contrary, as shown in FIGS. 3-4B of Winkler, the inner lumens (18a, 18b) of the catheter (12) do not extend throughout the catheter (12), but instead extend only to the inflation ports (48, 54) of the balloons (46, 52). Winkler thus lacks yet another limitation of claim 1.

Accordingly, independent claim 1 distinguishes over Winkler and represents allowable subject matter. Claims 15 and 37 are allowable at least because they depend from an allowable base claim.

Claim Rejections Pursuant to 35 U.S.C. § 103 – “Winkler / Zdeblick”

Claims 2-6, 11-13, and 38 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Winkler in view of U.S. Patent No. 6,375,655 (“Zdeblick”). Applicants respectfully disagree.

Each of the rejected claims depend ultimately from claim 1 and thus include all the limitations thereof. As explained above, Winkler is deficient with respect to claim 1 because it lacks the claimed support and the claimed conduit extending throughout a body. Since Zdeblick is equally deficient with respect to these limitations, the cited references fail to render any of claims 2-6, 11-13, or 38 obvious.

Zdeblick fails to remedy the deficiencies in Winkler with respect to claim 1 because it too lacks a body with a distal portion configured to selectively engage a support. As explained in Applicants’ most recent response and shown in FIGS. 9-10 of Zdeblick, the Zdeblick sleeve (52) is not in any way configured to selectively engage a support. In fact, the sleeve (52) does not even touch the support (10) of Zdeblick, much less selectively engage it.

Additionally, just like in Winkler, there is no conduit in Zdeblick that extends throughout a body, as further required by claim 1. Instead, as detailed in Applicants’ last response, FIG. 9 of Zdeblick shows that fluid cannot be passed or conveyed through any part of the sleeve (52) when it is assembled with the shaft (51) to form an implant driver (50). Rather, the shaft (51) and a threaded interface (65) completely fill the inner lumen of the sleeve (52) and block its proximal opening. Therefore the sleeve (52) of Zdeblick cannot be considered a body with a conduit that extends throughout and Zdeblick fails to remedy yet another deficiency in Winkler with respect to claim 1.

Accordingly, neither Winkler nor Zdeblick disclose the claimed support or the claimed conduit extending throughout a body. Claims 2-6, 11-13, and 38 are therefore non-obvious in light of these references and represent allowable subject matter.

Claim Rejections Pursuant to 35 U.S.C. § 103 – “Winkler / Zdeblick / Marchosky”

Claim 24 is rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Winkler in view of Zdeblick and further in view of U.S. Patent No. 6,413,278 (“Marchosky”). Applicants respectfully disagree.

Claim 24 recites a kit for providing a fusion-promoting material that includes an intervertebral fusion device and a flowable material. The intervertebral fusion device includes a body that defines a conduit that extends throughout the body. The distal portion of the body is configured to selectively engage a support.

Winkler, Zdeblick, and Marchosky cannot render the kit of claim 24 obvious because none of these references include a body that defines a conduit that extends throughout. As explained above, the Winkler conduits (18a, 18b) fail to extend throughout the Winkler body (12), instead stopping at a pair of inflation ports (48, 54). *Winkler* at FIGS. 3-4B. As also described above, in Zdeblick, a shaft (51) and a threaded interface (65) completely fill the inner lumen of the body (52), such that the body (52) has no conduit extending throughout. *Zdeblick* at FIG. 9. With respect to Marchosky, the only element or structure that defines a conduit, and thus the only structure that could form the claimed body, is a syringe (140) shown in FIG. 14. The Marchosky syringe however lacks a conduit that extends throughout because, just like in Zdeblick, it is filled by a shaft (160) and a threaded interface (148, 150). Accordingly, each of the cited references lack a limitation of claim 24 and therefore claim 24 is non-obvious.

Furthermore, none of the references cited by the Examiner disclose a body with a distal portion configured to selectively engage a support, as further required by claim 24. First, in Winkler, neither the support (20) nor the balloon (46) can be selectively engaged by a distal portion of the catheter (12). Instead, as noted above, the Winkler catheter (12) does not engage the support (20) at all, much less selectively. The Winkler balloon (46) on the other hand does engage the catheter (12), however it is permanently affixed thereto, not selectively engaged as required by claim 24. *Winkler* at FIG. 1. Zdeblick and Marchosky are likewise deficient. In Zdeblick, the sleeve (52) does not even touch the support (10), much less selectively engage it. *Zdeblick* at FIGS. 9-10. In Marchosky, the support is merely placed between two vertebrae after a separate tool performs cutting and distraction

steps. *Marchosky* at FIGS. 3, 21; col. 2, lns. 36-54. No body of any kind is used, much less a body with a distal portion capable of selectively engaging the support.


Accordingly, none of the references cited by the examiner teach the claimed body that defines a conduit that extends throughout or the claimed body with a distal portion configured to selectively engage a support. Claim 24 is therefore non-obvious and represents allowable subject matter.

Conclusion

Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicants' amendment of the claims does not constitute a concession that the claims are not allowable in their unamended form. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

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